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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/309,199	05/10/1999	MARIO ASSENMACHER	212302000720	7207

7590 03/19/2002

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EXAMINER

BELYAVSKYI, MICHAIL A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/309,199	ASSENMACHER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Michail A Belyavskyi	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 November 2001.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-115 is/are pending in the application.

4a) Of the above claim(s) 51-73 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-50;74- 115 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 5/10/99 is/are: a) accepted or b) objected to by the Examiner. *See PTO 948*  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: *Restriction/Election Fax sheet*.

Art Unit: 1644

#### DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644, Technology Center 1600.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 11/18/01 (Paper No. 18), has been entered.

3. Applicant's amendment, filed 11/8/01 (Paper No. 19), has been entered.

Claims 74-115 have been added.

Claims 1-3, 10-15, 19-22, 25, 27-28, 30-31, 34-35, 38, 42 and 47-48 have been amended.

Claims 1-115 are pending

Given the previous restriction, which is hereby reiterated; claims 51-73 stand withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-50 and 74-115 are being acted upon presently.

#### ***Restriction Requirement***

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-13, 74-87, drawn to a method for obtaining a cell population enriched in antigen-specific T cells, classified in Class 435, subclass 2, 374.
- II. Claims 14-21, 33, 88-97, drawn to method to label antigen-specific T cells, classified in Class 435, subclass 7.2, 373.

- III. Claims 22-28, 98, drawn to composition, comprising of labeled antigen-specific T cells, classified in Class 435, subclass 325
- IV. Claims 29-30, drawn to cells and progeny, classified in Class 424, subclass 93.1.
- V. Claim 31, drawn to a method of analyzing a population of cells, classified in Class 435, subclass 7.1.
- VI. Claim 32, drawn to a method of determining a distribution of secretory activity in a cell, classified in Class 435, subclass 375.
- VII. Claims 34-50, 99-115, drawn to a method for identifying antigen-specific T cells, classified in Class 435, subclass 326.

4. Groups III and IV are different products. The Group III contains a mixture of secretory active and naive cells and Group IV contains a specific population of activated T cells. These products are made by different methods and have different uses. The examination of the Groups will require non-coextensive searches; therefore each product is patentably distinct.

5. Groups (I and IV) and (II and III) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products, activated T cells can obtained by *in vivo* immunization and *in vitro* separation techniques other than that claimed .

6. Groups I, II, V-VII are different methods. A method for obtaining cell population, enriched in antigen-specific T cells, method to label antigen-specific T cells, method to analyze a secretory active cells among all cells in the population, method to determine a distribution of secretory activity in a cell population enriched in antigen-specific T cells and method to identify antigen-specific T cells differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

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***Species Election***

8. This application contains claims directed to the following patentably distinct species of the claimed Invention VII: wherein the cell surface molecule is selected from the group:

- A) CD2,
- B) CD3,
- C) CD4,
- D) CD5,
- E) CD8,
- F) CD11b,
- G) CD26,
- H) CD27,
- I) CD28,
- J) CD29,
- K) CD38,
- L) CD40L,
- M) CD45RO,
- N) CD45RA,
- O) LAG3,
- P) T1/ST2,
- Q) SLAM,
- R) Class I MHC,
- S) Class II MHC
- T) T cell antigen, or
- U)  $\beta_2$ - microglobulin.

These species are distinct because their structure and mode of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions VII: wherein detectable label is:

- A) fluorophore,
- B) radioactive isotope or
- C) chromophore.

These species are distinct because their structure and mode of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Art Unit: 1644

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.  
Patent Examiner  
Technology Center 1600  
March 15, 2002

*Phillip Gambel*  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
*Tech Center 1600*  
*3/18/02*